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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/687,517	10/16/2003	Edgar Hommann	33628/US	5234
7550 08/19/2008				
David E. Bruhn DORSEY & WHITNEY LLP Intellectual Property Department 50 South Sixth Street, Suite 1500 Minneapolis, MN 55402-1498		EXAMINER MEHTA, BHISMA		
		ART UNIT 3767		PAPER NUMBER
		MAIL DATE 08/19/2008		DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/687,517

Applicant(s)

HOMMANN ET AL.

Examiner

BHISMA MEHTA

Art Unit

3767

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 July 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6, 8, 9, 12, 13, 17 and 19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 8, 9, 12, 13, 17 and 19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S508)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 25 2008 has been entered.

Specification

2. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The specification fails to disclose the operating means formed as a one-piece lever comprising a lever arm and a protrusion. The specification also fails to disclose the releasing element projecting radially outward and extending through an opening.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 6, 9, and 12 are rejected under 35 U.S.C. 102(e) as being anticipated by Brunel (U.S. Patent No. 6,575,939). Brunel discloses an injection device having a casing (10), dispensing means (6), and operating means (7). The injection device also includes a dosing means with a releasing element (15) which projects radially outward and extends through an opening in the casing and an indicator for indicating a product amount (lines 11-14 of column 9). As seen in Figure 2, 8, 9, 11-13, and 16, the releasing element (15) is shown to project radially outward and extend through the opening (shown at 17 in Figure 2, also see lines 1-16 of column 6). The releasing element is moved from a first stopper on a first side of the opening to a second stopper on a second side of the opening which is opposite to the first side as seen in Figures 14 and 15. The dimensions of the opening limit the movement of the releasing element, thereby setting the predetermined amount of the dosage and the indicator counts down by a dosage unit when the releasing element is moved (lines 34-39 of column 5 and lines 11-14 of column 9). As to claim 12, a guiding means (26) is provided which is capable of guiding a needle cap to exchange the injection needle of the device.
5. Claim 13 is rejected under 35 U.S.C. 102(b) as being anticipated by Kirchhofer et al (U.S. Patent No. 6,258,068). Kirchhofer et al disclose an injection device having a casing (4, 7), a product container for fluid product (1), a holder (30) for the product container, an injection needle (N), and a needle protector. The needle protector

comprises a sleeve (10) which is arranged on the holder for the product container or the product container such that the sleeve is shiftable in a longitudinal axis with respect to the holder for the product container or the product container to generally surround the injection needle in an advanced position. The holder for the product container and the sleeve are insertable into the casing and removable from the casing to exchange the product container. The sleeve serves as a guide for a needle cap used to exchange the injection needle.

6. Claims 17 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Jacklich (U.S. Patent No. 4,444,560). Jacklich discloses an injection device has a casing (9) and operating means pivotable in a radial direction about a fulcrum (51) which is arranged laterally on the injection device. The operating means include a one-piece lever with a lever arm and a protrusion (65) where the protrusion is co-operative with dispensing means (61) via a surface oblique relative to a longitudinal axis of the device. Pivoting of the operating means allows the dispensing means to be moved in an axial direction. The device also includes a releasing element (57) for releasing a dosage amount where the release element projects through an opening in the casing. The dimensions of the opening limit movement of the releasing element and the dosage amount is released by moving the releasing element from a first stopper on a first side of the opening to a second stopper on a second side of the opening opposite the first side (Figures 2 and 3). As to claim 19, the sleeve (21) is considered to be capable of surrounding the injection needle and being shiftable.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jacklich (U.S. Patent No. 4,444,560) in view of Ronvig (U.S. Patent No. 5,433,352).

Jacklich discloses an injection device for administering a fluid product having a casing (9), a piston rod (61) for dispensing the fluid product from a product container (37), and operating means for operating the piston rod. The operating means are provided laterally of a circumferential surface of the casing and have a lever with a lever arm (11) and a protrusion (57). The protrusion projects substantially perpendicular from the lever arm as seen in Figure 1 towards a longitudinal axis of the injection device and is fed into the casing. The operating means is pivotable in a radial direction relative to the casing about a fulcrum (shown at 51) and the protrusion is co-operable with the piston rod via a surface oblique relative to a longitudinal axis of the casing. Jacklich discloses that pivoting the lever arm of the operating means causes the protrusion to move along the oblique surface and displaces the piston rod. As seen in Figure 1, the fulcrum is provided on the circumferential surface in a generally central area of the injection device. The oblique surface is provided on the piston rod or can also be considered to be provided on the protrusion. At least a portion of the protrusion is connected to the piston rod by a T-connection such that the protrusion and the piston

rod can slide relatively. As to claim 5, Jacklich discloses an indicator for indicating a product amount in the product container in the form of the ratchet teeth which are operated by pivoting the operating means (lines 40-44 of column 2). Jacklich discloses the device substantially as claimed. Even though Jacklich discloses a lever comprising a lever arm and a protrusion, Jacklich is silent on the specifics of the lever being a one-piece lever with a lever arm and a protrusion. Ronvig discloses an injection device having a one-piece lever comprising a lever arm and a protrusion. It would have been obvious to one having ordinary skill in the art at the time the invention was made to form the lever of Jacklich as a one-piece lever with a lever arm and a protrusion as taught by Ronvig as both Jacklich and Ronvig disclose injection devices with levers and Ronvig teaches that it is well known to use a one-piece lever.

9. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jacklich and Ronvig as applied to claim 5 above, and further in view of Cosmai. Jacklich and Ronvig disclose the device substantially as claimed. Even though Jacklich discloses administering the fluid product in doses and providing an indicator for indicating a product amount, Jacklich is silent on the injector comprising a scale up to a total number of dosages amounts present and counts down by one unit on the scale when the dispensing means or operating means is operated. Cosmai discloses an injection device having an indicator which comprises a scale (i.e. the markings) and counts down by a dosage unit when the dispensing means are operated. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the indicator of Jacklich with a scale as taught by Cosmai as both Jacklich and Cosmai

disclose devices for administering a fluid in doses and Cosmai teaches that it is well known to provide a scale so that the number of dose being administered may be monitored.

Response to Arguments

10. Applicant's arguments with respect to claims 1-5 and 8 have been considered but are moot in view of the new ground(s) of rejection.

11. Applicant's arguments with respect to claims 17 and 19 have been considered but are moot in view of the new ground(s) of rejection. With regards to Applicant's arguments in lines 12-21 of page 9 that Jacklich does not disclose a first stopper on a first side of the opening and a second stopper on a second side of the opening, the releasing element (57) is moved from a first stopper on a first side of the opening (the first side being above 65 in Figure 2) to a second stopper on a second side (49) of the opening. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the releasing element (57) contacting any portion of the casing) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

12. Applicant's arguments with respect to claims 6, 9, and 12 have been considered but are moot in view of the new ground(s) of rejection. With regards to Applicant's arguments in line 21 of page 10 to line 2 of page 11 that the releasing element (15) of

Brunel does not project radially outward and extend through an opening, the releasing element (15) does project radially outward and extend through an opening as seen in the figures. The opening in the casing is shown at 17 in Figure 2.

13. Applicant's arguments with respect to claim 13 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BHISMA MEHTA whose telephone number is (571)272-3383. The examiner can normally be reached on Monday through Friday, 7:30 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Simons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

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USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bhisma Mehta/

Examiner, Art Unit 3767

/Kevin C. Simons/

Supervisory Patent Examiner, Art Unit 3767